



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0736]

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 24, 2015, from 8 a.m. to 6 p.m.

Addresses: FDA is opening a docket for interested persons to submit electronic or written comments regarding this meeting. The docket number is FDA-2014-N-0736. Please see the Procedure section of the notice for further information.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability,

visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Shanika Craig, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, Shanika.Craig@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 24, 2015, the committee will discuss the risks and benefits of Bayer HealthCare's Essure System for permanent female sterilization. The system, originally approved in November 2002, under P020014, consists of a delivery system and nickel-containing permanent implants. The implants are placed without a skin incision, through the vagina, within each fallopian tube; they elicit tissue ingrowth, which over time results in tubal occlusion.

FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of the Essure System. The committee will be asked to evaluate currently available scientific data pertaining to the safety and effectiveness of the Essure System, such as events related to implant perforation/migration, device removal, chronic pain, allergic reactions, and unintended pregnancy. The committee will be asked to provide recommendations regarding appropriate device use, product labeling, and potential need for additional postmarket clinical studies.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at

<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

CDRH plans to provide a live Webcast of the September 24, 2015, meeting of the Obstetrics and Gynecology Devices Panel. While CDRH is working to make Webcasts available to the public for all advisory committee meetings held at the White Oak campus, there are instances where the Webcast transmission is not successful; staff will work to re-establish the transmission as soon as possible. The link for the Webcast is available at:

<https://collaboration.fda.gov/gudpm052015/>. Further information regarding the Webcast, including the Web address for the Webcast, will be made available at least 2 days in advance of the meeting at the following Web site: <https://collaboration.fda.gov/ogdp2015/>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 4, 2015. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. on September 24, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 24, 2015. Time allotted for each presentation may be

limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 28, 2015.

FDA is opening a docket for public comment on this document. The docket will close on October 24, 2015. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Comments received on or before August 31, 2015, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you

require special accommodations due to a disability, please contact Ann Marie Williams, at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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